



## Urgent Field Safety Notice Product Correction Immediate Action Required

**Date Issued** April 30, 2014

**Product**

Product	List Number (LN)	Lot Number	Expiration Date
Hemoglobin A1c (HbA1c) Calibrators	4P52-02	45063UQ12	15 DEC 2014

**Explanation**

HbA1c Calibrators LN 4P52-02, lot 45063UQ12 may contain a value sheet for a different HbA1c calibrator lot.

If calibrator lot 45063UQ12 is used in the calibration of the HbA1c assay using values from an incorrect calibrator value sheet then all results, including quality control and patient, may be falsely elevated.

**Patient Impact**

Patient results could be falsely elevated up to an 8% difference due to the use of incorrect calibrator values.

**Necessary Actions**

The HbA1c Calibrators package insert instructs you to **verify that the lot number listed on each calibrator bottle agrees with the lot number printed on the value sheet.**

- Before using HbA1c Calibrators lot 45063UQ12, verify that the value sheet lot number matches the calibrator bottle lot number.
  - If HbA1c Calibrators lot 45063UQ12 has already been utilized in your laboratory, verify the concentrations configured for this calibrator lot match the values below.
  - If these do not match, use the values below when calibrating the HbA1c assay using calibrator lot 45063UQ12.

<b>LOT</b> 45063UQ12	<b>Exp.</b> 2014-12-15	<b>REF</b> 4P52-02
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REAGENT	REF	HbA <sub>1c</sub>	THb
<b>CAL 1</b>	4P52-02	3.02 µmol/L	99.4 µmol/L
<b>CAL 2</b>	4P52-02	16.00 µmol/L	155.8 µmol/L

- Follow your laboratory protocol regarding the need for reviewing previously reported patient results if incorrect calibrator values were used.

Please retain a copy of this letter for your laboratory records. If you have forwarded any of the lot above to another laboratory, please provide a copy of this letter to them.

**Contact Information**

We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.